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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/648,047

08/26/2003

Bill H. McAnalley

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EXAMINER

MOSS, KERI A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

01/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/648,047 | <b>Applicant(s)</b><br>MCANALLEY ET AL. |  |
|                              | <b>Examiner</b><br>KERI A. MOSS      | <b>Art Unit</b><br>1797                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5,8,11-22 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,8,11-22 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Amendment*

1. Previous rejection in view of Fleischner, Brand and Cho have been maintained in light of applicants amendments and arguments.

### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims **1, 5, 8, 11-22 and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischner (USP 6,291,533) in view of Brand et al. (An Outstanding Food Source of Vitamin C, The Lancet, Vol. 320 Issue 833, p. 873) and further in view of Cho et al. (US Pub 2002/0192314). Fleischner teaches an antioxidant composition comprising a flavonoid such as isoflavone or a flavonol such as quercetin, a mixture of two forms of Vitamin E, Vitamin C, polyphenols, green tea extract and a carrier such as aloe vera gel extract (columns 7-8).
3. Fleischner does not teach a ratio of flavonoid to mixture of vitamin E forms as 40/60 to 90/10 percent by weight. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) teaches that optimization of a result-effective variable is ordinarily within the skill of one in the art. A result-effective variable is one that has well-known and expected results.

The selection of percentage by weight of any ingredient in the antioxidant composition are result effective variables. Varying the percentage by weight of any

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ingredient has the well-known and expected result of producing the desired result of the ingredient (i.e. improved cardiovascular health, delay of cholesterol oxidation) in a composition of a varied size. Therefore, it would have been obvious to one of ordinary skill in the art to meet the percentage by weight requirements of claimed ingredients such as flavonoid such as isoflavone or a flavonol such as quercetin, a mixture of two forms of Vitamin E, green tea extract comprising 36% catechin & polyphenols and a carrier such as aloe vera gel extract by modifying Fleischner and selecting the flavonoid/vitamin E mixture percentage by weight of 40/60 to 90/10 in order to control for the desired result and control the size of the composition.

Fleischner does not teach a source of vitamin C and does not disclose a composition additionally comprising bush plum pulp and skin comprising 5% vitamin C. Brand et al. disclosed in 1982 that bush plum pulp and skin is an outstanding source of Vitamin C (p.873). Thus, one needs only a small amount of this fruit to meet the daily requirements of vitamin C. Adding an ingredient with a high proportion of the nutrient is ideal for nutritional supplements as it keeps the size of the supplement small while adding a higher concentration of the desired ingredient. It would have been obvious for one of ordinary skill in the art to modify Fleischner with the teachings of Brand et al. by using the edible parts of bush plum as the source of vitamin C so as to keep the size of the supplement small while adding enough vitamin C to meet the intended nutritional requirements. While Brand et al. do not teach a percentage of vitamin C of 5% in the edible fruit, it is within the knowledge of one with ordinary skill in the art to modify the percentage of a nutrient in an ingredient for the desired effect.

Fleischner does not disclose a supplement additionally comprising grape skin extract comprising 30-82% polyphenols. Cho et al. teaches a dietary supplement comprising grape skin extract ([0012]) comprising polyphenols of between 25 and 100%, within applicant's disclosed range ([0016]). Grape skin extracts have known antioxidant properties, specifically known to inhibit LDL cholesterol oxidation ([0012]). It would have been obvious to modify the teachings of Fleischner by adding grape skin extracts in 25-100% polyphenols order to gain the advantages of the antioxidant properties.

#### ***Response to Arguments***

4. Applicant's arguments filed October 14, 2008 have been fully considered but they are not persuasive. First, Applicant has not provided evidence that the Examiner did not consider all the words in the claim. Examiner's previous arguments regarding percentage by weight is a general statement that addresses applicants' amendments. Second, in response to applicant's argument that the Examiner has not shown predictable results, the Examiner has shown that these products are known antioxidants that can be used as nutritional supplements. There is no reason for one of ordinary skill in the art to believe that these nutritional supplements can not be combined. Therefore, the rejection is maintained.

***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/  
Primary Examiner, Art Unit 1797

/Keri A. Moss/  
Examiner, Art Unit 1797